

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Michel PAIRET, et al.

Examiner: Carlie K. Huynh

Serial No.: 10/776,757

Group Art Unit: 1617

Filed: February 11, 2004

Confirmation No.: 3466

Title: PHARMACEUTICAL COMPOSITIONS BASED ON ANTICHOLINERGICS
AND CORTICOSTEROIDS

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action mailed May 21, 2007, applicants have the following elections. A request for a 2-Month Extension of Time is filed herewith.

Initially, it is noted that applicants filed a Preliminary Amendment concurrent with the filing of this continuing application on February 11, 2004. The Restriction/Election of Species requirement does not take into account the amendments made thereby. Currently, claims 1, 3-10, 15-39, and 63-66, as amended are pending. Applicants will attempt to make the elections within the framework of the Restriction/Election of Species requirements as best as possible given the different nature of the claims. The claims have been amended to direct them to inhalable powders.

The Restriction Requirement

In response to the restriction requirement, applicants hereby elect Group II, claims 1-39, 49-58 and 61-66, drawn to a propellant-free pharmaceutical composition comprising an anticholinergic and a steroid, and to capsules and kits containing such composition. As pointed out above, the claims are already amended to direct them to inhalable powders which do not contain a propellant. The election is made with traverse for the reasons set forth

below. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter.

Applicants respectfully traverse the restriction between Groups I and II since Group I is no longer encompassed by the claims. The restriction requirement is believed to be rendered moot by the Preliminary Amendment of the claims.

In any event, applicants submit that the allegation that Groups I and II, as set forth, are unrelated is not supported on the record. These inventions are clearly related. Although they differ as to whether a propellant is present, the combination of active ingredients is the same in both Groups. Accordingly, it is not supportable that the Groups I and II are unrelated and the restriction between Groups I and II should be withdrawn.

As for the method of use claims, these claims were canceled in the Preliminary Amendment, thus, the restriction thereof is rendered moot.

For all of the above reasons, it is urged that the restriction requirement should be withdrawn, in total.

The Election of Species Requirement

In response to the requirement for an election of species, applicants again note that the claims have been amended. The requirement in the Office Action for selecting certain defined aspects of the composition, as the elected species, does not coincide with the current claims. To further the prosecution, applicants hereby elect the following species of a composition within the scope of the current claims. Applicants elect a composition of an inhalable powder as described by formulation example A4 (page 21) containing:

- tiotropium bromide as the anticholinergic,
- ciclesonide as the steroid, and
- lactose as an excipient.

It is noted that the invention of the claimed inhalable powder compositions in its broadest sense does not require the presence of an acid, solvent or excipient (see, e.g., pages 8-9, of the specification). Thus, while an excipients such as lactose is preferred and recited for the elected species, no acid or solvent is recited since such is not preferred for an inhalable powder. It is believed that claims 1-4, 6-10, 20-24 and 26-34 encompass the elected species.

The Examiner is encouraged to examine the broadest possible scope of invention

indicated by the elected species. In accordance with M.P.E.P. §803.02, the Examiner is reminded that, should no prior art be found which renders the invention of the elected species unpatentable, the search of the remainder of the generic claim(s) should be continued in the same application. It is improper for the PTO to refuse to examine in one application the entire scope of the claims therein unless they lack unity of invention. The generic claims herein have not been alleged to lack unity of invention.

Favorable action is earnestly solicited.

No fee, other than the 2-Month Extension of Time being paid herewith, is believed to be due with this Amendment. However, the Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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JAS/cak